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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/681,013
Filing Date: October 07, 2003
Appellant(s): KAUVAR ET AL.

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For Appellant

EXAMINER'S ANSWER

This is in response to the Appeal Brief filed April 9, 2007, appealing from the Office action mailed April 19, 2006.

(1) Real Party in Interest

The Appeal Brief identifies "Trellis Biosciences, Inc." as the Real Party in Interest.

(2) Related Appeals and Interferences

Examiner is aware of the following related appeals, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Kauvar	10/714163	Protein Localization Assays for Toxicity and Antidotes Thereto
Kauvar	11/003675	Homogeneous Competition Assays

(3) Status of Claims

The statement of the status of claims contained in the Appeal Brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the Appeal Brief is deficient because the summary describes unclaimed subject matter. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include a concise explanation of the subject matter defined in each of the independent claims involved in the appeal.

Specifically, the summary uses the term "hue" to describe the claimed composition. However, the term "hue" does not appear in any claim under appeal.[1]

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[1] A prior version of claim 1 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the term "hue". Subsequently, the term "hue" was deleted from claim 1 in Applicants' Amendment filed May 31, 2005.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the Appeal Brief is correct.

(8) Evidence Relied Upon

Nie *et al.*	U.S. PAT. APPN. PUB. NO. 2003/0148544	08-07-2003
Kauvar *et al.*	U.S. PAT. APPN. PUB. NO. 2001/0044116	11-22-2001

(9) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections set forth in this Examiners Answer:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Nie *et al.* (US 2003/0148544).

Nie *et al.* describes a composition comprising a multiplicity of different labels (see para. [0022], "QD-tagged beads"), wherein each label consists essentially of a particulate support which support is coupled to:

> (a) a first characterizing signal-generating moiety which moiety comprises one or more entities that emit one or more wavelengths that compose a visible signal (see para. [0022], "\ Cross-hatchings"; "X cross-hatchings") (internal quotations omitted); and
>
> (b) a second signal generating moiety consisting of a single fluorophore directly attached to said particulate support which second signal-generating moiety emits a signal of the same wavelength at the same intensity from all of said different labels (see para. [0022], "/ cross-hatchings") (internal quotations omitted);
>
> wherein the wavelength of the signal generated by said second signal-generating moiety (see para. [0022], "/ cross-hatchings indicate green quantum dots") (internal quotations omitted) is different from the one or more wavelengths that compose the characterizing signal (see para. [0022], "\ Cross-hatchings indicate red quantum dots"; "X cross-hatchings indicate blue quantum dots") (internal quotations omitted); and
>
> wherein said labels further contains at least one reagent that binds specifically to a target (see para. [0022], "[p]robe oligos").

With respect to composition claims 1, 2 and 7, the following claim language from claim 1 is not afforded patentable weight because the language does not appear to materially structurally alter the composition of claim 1:

> "wherein each different label is directed to a different specific target" (line 2)
> "characterizing" (lines 4, 6 and 12)

"that characterizes said label" (line 6)

"which characterizing signal characterizes the label" (line 12-13)

With respect to claim 3, Nie *et al.* describe a method to determine the distribution of multiple target substances in a sample which method comprises contacting said sample with the composition of claim 1, wherein the number of labels at a location in the sample is assessed by measuring the intensity of the clamped value signal emitted from the second signal generating moiety (see Fig. 5, para. [0069], "The intensity of the signal generated by the tag attached to the target molecule will be in direct proportion to the amount of target present in the sample").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nie *et al.* (US 2003/0148544) is view of Kauvar *et al.* (US 2001/0044116).

Nie *et al.* describe a method for providing a pattern of target substances as substantially described *supra.*

Nie *et al.* do not describe a method wherein the sample comprises intracellular environment or neural circuitry.

However, Kauvar *et al.* disclose a method using microscopy (See Fig. 1) to view intracellular targets (see p. 6, para. (0062], "cell or dendrites"') or neural circuitry (See p. 6, para. (0062], "dendrites").

It would have been obvious for a person of ordinary skill in the art to adapt Nie's method of determining target distribution with intracellular or neural microscopy because Kauvar *et al.* provide a method of organizing observations in following physiological pathways. A skilled artisan would have had a reasonable expectation of success in using the labels of Nie *et al.* in a method for viewing an intracellular environment because Nie *et al.* teach that the use of multicolor optical coding using luminescent QDs offers important advantages and applications that are not possible with other types of dyes (see para. [0017]). Nie *et al.* also teach that by using their labels, particulate beads can be quantified based on the observed number of quantum dots, i.e. intensity multiplexing.

(10) Response to Argument

Appellants argue:

1. Nie *et al.* fail to disclose the composition of claim 1.
2. Nie *et al.* fail to disclose a method wherein "the number of labels at a location in the sample is assessed by measuring the intensity of the signal emitted from the second signal generating moiety attached to said particulate supports" as recited in claim 3.
3. Appellants' case is similar to the case in *Glaxo, Inc. v. Novopharm, Ltd.*, 34 U.S.P.Q.2d 1565 (Fed. Cir. 1995).
4. Kauvar *et al.* teach away from Appellants' claimed invention.

Appellants' arguments are not persuasive.

With respect to argument 1), Nie *et al.* describe each and every element of claim 1, as set forth *supra*. Briefly, Nie *et al.* describes a composition comprising a multiplicity of different labels (see para. [0022], "QD-tagged beads"). Each label has (a) a first signal-generating moiety emitting a visible signal (see para. [0022], "\ Cross-hatchings"; "X cross-hatchings") (internal quotations omitted); and (b) a second signal generating moiety consisting of a single fluorophore emitting a different signal at the same intensity from all of said different labels (see para. [0022], "/ cross-hatchings") (internal quotations omitted). Each label contains at least one target-specific reagent that binds a target (see para. [0022], "[p]robe oligos").

With respect to argument 2), Nie *et al.* vary the ratio of the concentration of signal-generating moieties in their labels (see *e.g.*, Fig. 5) in order to detect different target molecules (see *e.g.*, paragraph [0078]). In order to detect these labels, Nie *et al.* expressly acknowledge at paragraph [0069] the relationship between signal intensity of signal-generating moieties versus the number of labels and graphically depict this relationship in Fig. 2a. Such a relationship between signal intensity versus number of a signal-generating moiety is common knowledge among persons of ordinary skill and is embodied in the widely known Beer's Law and applies to all signal-generating moieties present in all labels, including all the signal-generating moieties present in all labels described in Fig. 5 and paragraph [0022].

With respect to argument 3), the Court of Appeals for the Federal Circuit in *Glaxo* upheld the District Court's rejection of a Doctrine of Inherency defense to infringement. However, the decision in *Glaxo* does not apply here because Examiner does not rely on the Doctrine of Inherency to reject any of claims 1-7. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(e) as being expressly anticipated by Nie *et al.* (US 2003/0148544), as set forth *supra*.

With respect to argument 4), Examiner does not understand Appellants' reasoning set forth in the Appeal Brief as to how paragraph [0062] of Kauvar *et al.* (US 2001/0044116) is inappropriate or teaches away from Appellants' invention. To the contrary, paragraph [0062] provides motivation by providing a method of organizing observations in following physiological pathways, which is one of Kauvar's inventive accomplishments: improved *in situ* label detection in microscopy (see *e.g.*, para. [0005], [0007]).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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